Processed Apples Institute, Inc.



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August 11, 2000

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

Via Federal Express

Re: Docket Number OOD-1305

The Processed Apples Institute (PAI) is an international trade association representing domestic and foreign processors of apple products including apple juice, apple juice concentrate and other apple products. Our members are vitally interested in regulations, U.S. and international, which establish enforcement guideline levels for patulin in processed apple products that are consistent with sound public health policy and which do not infringe upon trade of these healthful foods.

Many PAI members have implemented patulin control programs. The key elements include grading and testing of raw fruit followed by mechanical scrubbing. Subsequent product testing has indicated that the program has been successful as the majority of patulin levels do not exceed 50 μ g/Kg (50 ppb). FDA's safety assessment for patulin supports establishment of a 50 ppb action level. PAI comments that the analytical data collected supports this proposal and recommends its adoption.

Our recommendation to adopt the 50 ppb action level is consistent with PAI's previous actions and comments. In January 1997, PAI submitted comments to FDA in support of a National Food Processors Association's recommendation that FDA adopt an action level of 50 ppb for patulin. The above identified docket points out the Center for Food Safety and Applied Nutrition Scientific Advisory Committee (SAC) supported the 50 ppb proposed action level. PAI presented data and participated in the public hearings completed by the SAC as part of the SAC review of patulin. PAI commented in support of the 50 ppb proposal in their remarks to the SAC.

PAI also notes the conclusions of the Joint FAO/WHO Expert Committee on Food Additives, which reviewed patulin at its 36^{th} and 44^{th} sessions and established tolerable weekly and daily intakes. FDA cites these actions in the docket listed above. The toxicologic data base and residue data supported the U.S. recommendation that a maximum level of 50 μ g/Kg for patulin in apple juice be adopted in international specifications without further study. (October 21, 1998 letter to Mr. E.F.F. Hecker,

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Chairman, Codex Committee on Food Additives and Contaminants [CCFAC] from Dr. F. Edward Scarbrough, U.S. Manager for Codex.) The 50 $\mu g/Kg$ proposal was adopted at the 32nd session of the CCFAC in March 2000 and submitted to the Codex Alimentarius Commission with a recommendation it be adopted at Step 8 of the Codex Alimentarius Procedures. Thus, the FDA proposal identified in the above cited docket is in agreement with international food regulations.

PAI member organizations will continue to monitor their products, will continue to strive for the lowest levels of patulin practical and possible and comment in favor of adopting the 50 μ g/Kg (ppb) action level proposed for patulin in apple juice, apple juice concentrate and apple juice products.

Sincerely,

Andrew G. Ebert, Ph.D.

Andrew G. Spers

cc: Dr. T. Troxell

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